REMARKS

Claims 10 and 14 have been amended. New Claim 13 has been added. Claims 10-16 remain in the application. Reexamination and reconsideration of the application as amended are respectfully requested. The Examiner's comments are shown in bold.

Introductory Remarks:

The Examiner has rejected Claims 10-16 on the basis of 35 U.S.C. 112, first paragraph. In a paper received by the PTO on Aug 23, 2004, the Applicant respectfully traversed these rejections, and in accordance with the provisions of 37 CFR 104 (d) (2) requested an affidavit from the Examiner which supports the Examiner's 112 rejections. This Examiner affidavit will then be contradicted in affidavits from the Applicant as well as others skilled in the test device art. However, until the Examiner affidavit is received, the following response is offered in rebuttal to the Examiner's 112 rejections.

Claim Rejections - 35 USC § 112, first paragraph

3. Claims 10-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, which being enabling for a method for detecting human blood using labeled anti-Hb antibodies which are captured and detected, does not reasonably provide enablement for labeled anti-Hb antibody in which the label is released from the antibody thereby providing a visual indication. . .

Regarding Item 3:

While providing several general statements regarding perceived deficiencies in the present application, the Examiner makes the following specific points:

(1) The specification does not teach how these labels are conjugated to the antibodies such that binding of a complex comprising hemoglobin and labeled antibody to an

immobilized capture reagent allows the labels, i.e. enzymes, to be released from the antibodies thereby providing a visual indication; and,

(2) Generally, neither labels such as enzymes nor particulate labels is released from the antibody--In instances where labels are released, as set of specific condition must be met before such labels are operable--that in order for the signal from the labels to be read, reagents must be employed.

Regarding (1) above, the conjugation of labels to antibodies is well known to those skilled in the assay test art. Many conjugation techniques are available. Conjugation typically encounters no difficulties in creating bonds to link the antigen and the colloid. Generally acceptable theory is that the residues of three particular amino acids play an important role in binding proteins to gold particles. Each of these amino acids—lysine, tryptophan, and cysteine—operates by a different mechanism to bring about conjugation. For example:

a.. Lysine is highly positively charged and therefore naturally attracted to a negatively charged gold particle.

b.. Tryptophan works through hydrophobic interactions.

c.. Cysteine creates dative bonds through the formation of sulphur bridges with the gold surface, such that the antibody and gold particles share electrons. Of all the forces controlling the attachment of antibodies to gold particles, this is the strongest, most permanent, and most difficult to break.

As is stated in the specification, the labels may include colloidal gold, colloidal silver, carbon, latex, dye, and enzymes. For example, gold particles between 40 and 100 nm could be conjugated successfully to the antibodies. The larger 100 nm particles are certainly more visible than the 40 nm particles, but there are fewer particles in a 1-ml solution at an optical density of 520 nm, so fewer of them can be packed onto the capture line. Overall, this usually expresses itself as a loss of signal at lower levels of hemoglobin (between 0 and 0.05 ug/ml), when compared with the same antibody conjugated to a 40- or 60-nm colloid but after some optimization work, one can potentially use any size but may have to compromise cost-benefit ratio.

Additionally, the Examiner's attention is drawn to the patents cited in the "BACKGROUND ART" section of the specification of the present application, and further to U.S. Patent 6,686,167. These patents, and numerous others issued by the USPTO, teach techniques of labeling.

Regarding (2) above, the Examiner appears to be saying that labels cannot be released unless a reagent is present. The Applicant respectfully disagrees with the Examiner's position. In the present invention, labels are release as is described in the specification, and the release does not require the presence of another substance.

4. Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Item 4., Paragraph 2:

The Examiner states **"Claims 10 and 14 are vague and indefinite because it is unclear how releasing the labels from the antibodies provide a visual indication. It would appear that once the labels are released from the antibodies, they are no longer localized in the detection zone and would therefore migrate away from such zone, thus any color that developed would be lost".**

The visual indications comes about through the mechanisms of hydrophobic interactions, hydrogen bonding, or electrostatic interactions. As soon as the color is released, it is likely absorbed/adsorbed on the membrane. Some (but not all) of the labels may get washed away if there is an excess of it causing the entire window to have a pinkish background color but the concentrated pinkish color in the specific test region location would still clearly give a positive indication.

Additionally, the Applicant knows of no patent statute or other governing document which requires an explanation of the mechanism of how or why an invention works before a

patent may be granted. If there is such a statute or document, the Applicant most respectfully request that it be provided by the Examiner.

Regarding Item 4., Paragraph 3:

The Examiner states **"Claims 10 and 14 also lacks a correlation between observation step and the preamble of the claims, i.e. does the observation of visual indications confirms the presence of absence of the human blood?. . . "**

The Applicant has amended the last clause of Claims 10 to read:

observing said visual indications at both said test station and said control station, thereby confirming the presence of human hemoglobin.

and, that the last clause of Claim 14 to read:

observing no visual indication at said test station, and observing said visual indication at said control station, thereby confirming a lack of presence of human blood.

Hopefully, this will correct the problem.

Regarding Item 4., Paragraph 4:

The Examiner states **"Claims 11 and 15 are vague and indefinite because it is unclear what the role of the IgM is. . ."**

The Applicant knows of no patent statute or other governing document that requires an explanation of the mechanism of how or why an invention works before a patent may be granted. f there is such a statute or document, the Applicant most respectfully request that it be provided by the Examiner.

In any case, IgM appears to enhance test device performance by eliminating the effect of interfering substances, particularly in forensic applications. For example when the forensic samples containing human hemoglobin are contaminated with soil debris or samples that are Luminol treated, off of plant material, Coomasie Blue treated, off of leather, Ninhydrin treated, from washed jeans, bleached or tide detergent treated etc.

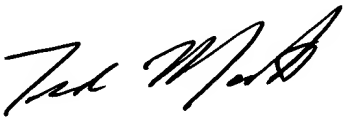
In closing, the Applicant respectfully points out that U.S. Patent No. 6,686,167 contains a specification and claims which are almost identical to those of the subject application. It would seem inconsistent for the USPTO to deem the disclosure of one application to be sufficient, and then take the position that an almost identical application does not provide a sufficient disclosure.

Form PTO-948 was not included in the Office Action, therefore the Applicant assumes that the drawings are acceptable.

A fee of $55 is included for a one month extension.

In view of the above, Applicant respectfully requests allowance of all the claims remaining in the application.

Respectfully submitted,



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